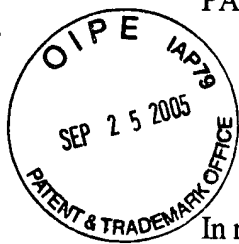


Attorney Docket No.: 99.45
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Maes et al.

Serial No.: 09/554,984

Group Art Unit: 1616

Filed: 05/23/2000

Examiner: A. Pryor

For: Lipid Blend For Skin Barrier Repair

APPELLANT'S BRIEF PURSUANT TO 37 CFR 1.191 AND 1.192

Assistant Commissioner of Patents and Trademarks
Attention: Board of Patent Appeals and Interferences
Washington, D.C. 20231

Dear Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 2 to 36 in the present application in the decision of August 25, 2004.

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REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Color Access, Inc., the assignee of the application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

STATUS OF THE CLAIMS

Claims 2, 4, 6-13, 15-26 and 28-36 are pending in this Application, and are included in this Appeal. Claims 1, 5, 14 and 27 were cancelled; claims 2, 3, 7, 16, 17, 20 and 23 were amended, and claims 29-36 were added in a response to a second office action dated January 30, 2003. Claims 2-4, 6-13, 15-26, and 28-30 were elected in response to an election requirement, but such an election was not acknowledged in subsequent office actions. In a facsimile dated July 21, 2004, claims 3, 7 and 34 were cancelled and claims 6, 10, and 15 in response to the Examiner's suggestion that such amendments would render the claims allowable.

GROUPING OF CLAIMS

For purposes of determining patentability, claims 2, 4, 6-13, 15-26 and 28-36 drawn to related issues of the present appeal, are grouped together and all grounds of rejection which Appellants contest apply to these claims. Specifically, claims 2, 4, 6-13, 15-26 and 28-36 are grouped together as they apply to the grounds of rejection based on 35 U.S.C. §103(a).

STATUS OF AMENDMENTS

The Amendment filed on July 21, 2004, in response to Examiner's request and as an Examiner's Amendment, was believed to be entered prior to the issuance of the final office action. All pending claims, a copy of which is attached hereto, are included in this appeal. A copy of all claims believed to be pending (2, 4, 6-13, 15-26 and 28-36), in this Appeal, also is attached hereto.

SUMMARY OF THE INVENTION

The invention concerns the discovery that the combination of a protease inhibitor and a cell differentiation enhancer can be used to enhance and strengthen the skin's naturally occurring lipid barrier. The activity of this combination allows compositions containing them to be used in a variety of skin treatment methods, for example, in treating dry skin, protecting the skin from the effects of irritants and UV exposure, and enhancing the process of self-tanning.

ISSUE

The outstanding issues are whether claims 15, 28-30 and 32 are rendered obvious by Simon et al. (U.S. Patent No. 5,932,234) (“Simon”), whether claim 10 is rendered obvious by the combination of Simon with Elias et al. (U.S. Patent No. 5,885,565) (“Elias”), and whether claims 2,3,6,8,16,17,20,23,26,33-36 are rendered obvious by the combination of Simon with Subbiah (U.S. Patent No. 6,150,381) (“Subbiah”). Specifically, the question is whether one skilled in the art would have any motivation to select the specific combination in the present invention from the laundry list of ingredients in the cited references for damaged lipid barrier, and therefore, for maintenance of normal and healthy lipid barrier.

ARGUMENTS

I. Prosecution History

A first rejection was mailed on August 14, 2001. The Office Action rejected claims 1-5, 7-9, 14, 16-18, 20, 21, 23, 24, 26 and 27 as obvious. After an argument submitted on April 15, 2002, the obviousness rejection was maintained in a second office action issued on October 31, 2003, wherein claims 6, 10-13, 15, 19, 22, 25 and 28 were objected to and deemed allowable if rewritten in independent form. In response, Applicants submitted an amendment and response on January 30, 2003, incorporating the subject of the rejected base claim 1 into claims 6, 10, and 15, each indicated as allowable if made independent with the subject of rejected claim 1 incorporated therein. Claims 2, 3, 4, 7, 8, 9, 16, 17, 18, 20, 21 and 23 were amended to depend directly or indirectly from allowable claim 6, claims 11-13, 19, 22 25 and 26 depend directly or indirectly from allowable claim 10 and claim 28 depends from allowable claim 15. New claims 29-36 indentically reflected the subject matter of original claims 2-9, written to depend from allowable claim 10. Despite the office action of October 31, 2003, wherein Examiner stated that such amendments would render the claims allowable, the Examiner again rejected the claims in a third office action dated May 19, 2003. Examiner did not comment on Appellants' amendments which Examiner had indicated would render the claims allowable and instead invoked an election requirement. Although such an election requirement was believed to prejudice Appellants at such a late stage in prosecution and was believed to unduly burden and delay prosecution of Appellants' application, Appellants reluctantly elected claims 2-4, 6-13, 15-26, and 28-30 on August 19, 2003. In an office action dated October 30, 2003, Examiner made no mention of Appellants' election and rejected claims 2, 3, 6-8, 10, 15-17, 20, 23, 26, 28-30, 32-36 as obvious in light of Simon, Subbiah, and Elias. The office action stated that claims 4, 9, 11-13, 18, 19, 21, 22, 24, 25 and 32 were objected to but indicated as allowable if rewritten in independent form. In a response dated April 30, 2004, Appellants argued that the claims were not obvious in light of the cited reference. Examiner then initiated a teleconference on July 20, 2004 and indicated that claims would be allowable if claims 6, 10 and 15 were rewritten to incorporate the limitations of claims 3, 7 and 34 respectively.

In response, Appellants, for Examiner's convenience, on July 21, 2004, faxed the required amendments that Examiner indicated would render the application allowable.

Specifically, claims 6, 10, and 15 were further amended and claims 3, 7 and 34 were cancelled in the Amendment faxed on July 21, 2004. However, to Appellants' surprise, issued a final rejection on August 25, 2004, ignoring the amendments the Examiner had requested and maintaining the rejections previously sent on October 30, 2003.

The rejection of the claims, in pertinent part, was stated as follows:

Simon teaches a composition for skin application comprising a number of actives. The actives include compounds such as Asiatic acid (protease inhibitor) and dihydroxyacetone (tanning agent) and vitamin D derivative (cell differentiation enhancer). See column 5 line 49 - column 6 line 38. Simon does not exemplify an invention comprising all three compounds. However, it would have been obvious to one having ordinary skill in the art to make such an invention. One would have been motivated to do this since Simon suggests the combination.

Office Action, p. 2

Simon teaches all that is recited by claims 2, 3, 6-8, 16, 17, 20, 23, 26, 33-36 except for the invention comprising sclareolide and instant amounts of ingredients. However, Subbiah teaches a composition for skin application comprising sclareolide. See column 3 line 20 - column 4 line 65. It would have been obvious to one having ordinary skill in the art to modify the invention of Simon to include sclareolide. One would have been motivated to do this since both inventions are applied topically to treat dermal disorders.

Office Action, pp. 2-3.

In response to this final rejection, the Appellants filed a notice of appeal because the Appellants believe they have been unduly prejudiced and the prosecution has been unduly delayed by the Examiner's repeated requests for amendments, which Examiner each time claimed would place the application in a condition for allowance. However, despite Appellants continued efforts to submit the Examiner's requested amendments, the

Examiner ignored such amendments and maintained the rejections. It is also believed that the Appellants' application is non-obvious in light of the cited prior art.

Applicants now present their arguments on appeal.

II. The rejection of all pending claims in the application is improper

The outstanding issues on appeal are whether claims 15, 28-30 and 32 are rendered obvious by Simon et al. (U.S. Patent No. 5,932,234) ("Simon"), whether claim 10 is rendered obvious by the combination of Simon with Elias et al. (U.S. Patent No. 5,885,565), and whether claims 2, 3, 6, 8, 16, 17, 20, 23, 26, 33-36 are rendered obvious by the combination of Simon with Subbiah (U.S. Patent No. 6,150,381) ("Subbiah"). Specifically, the question is whether one skilled in the art would have any motivation to select the specific combination in the present invention from the laundry list of ingredients in the cited references for damaged lipid barrier, and therefore, for maintenance of normal and healthy lipid barrier.

The present invention relates to a specific combination of a protease inhibitor, a cell differentiation enhancer, and a self-tanning agent, DHA, which are highly effective in stimulating the repair of a damaged lipid barrier, and therefore, are shown to be useful as well in maintenance of a normal and healthy lipid barrier, as exemplified in independent claim 15.

The Appellants traverse the Examiner's reasoning with regard to patentability of claims 15, 28-30 and 32, that although Simon fails to teach or suggest any specific combination of the laundry list of approximately sixty (60) specific actives and their variants, theoretically yielding thousands if not millions of combinations, that since Simon lists such a laundry list including actives from the Appellants' claims, that such a combination is obvious. In establishing a prima facie case of obviousness, there must be a motivation or suggestion in the prior art other than from the Appellants' disclosure to combine the references. See In re Rouffet, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). The Appellants submit that the Examiner has failed to present a prima facie case of obviousness because the specific combination of the Applicants' claims are not taught or suggested in the prior art. Moreover, Appellants' specification, Example 1,

provides unexpected results for such a combination. It is well established law that evidence of unexpected results is evidence of nonobviousness in order to rebut an obviousness rejection. See eg., In re Soni, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995) ([W]hen an applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary).

In contrast, Simon merely discloses a laundry list of possible actives that may be used in a composition. Specifically, Simon lists numerous broad categories of actives, as well as over 60 specific actives, including variations of such actives. Simon offers no teaching or even mere suggestion as to which combinations would be effective in a topical solution. Instead, Simon teaches a multitude of different materials that could be used alone or in any random combination, leading to a possibility of thousands if not millions of combinations. A person of ordinary skill in the art would have no motivation to randomly select three specific types of ingredients from the vast number of actives listed in Simon absent hindsight reconstruction using the Applicants' claims. The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. See In re Jones, 958 F.2d 347, 350, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992). Moreover, a generic disclosure having many variables, and encompassing millions of different species, does not render obvious a combination of three specific compounds, absent some motivation to select the specific species claimed. See In re Baird, 16 F.3d at 382, 29 U.S.P.Q.2d at 1552 (The Court found no evidence of motivation to select the claimed species, because there was nothing in the disclosure of the prior art suggesting that one should select such variables in a formula having many variables, encompassing more than a 100 million different diphenols, only one of which was bisphenol A. Therefore, the Court held that the prior art disclosure of millions of compounds does not render obvious a claim of three compounds.)

The Appellants submit that the Examiner has relied upon mere hindsight reconstruction to pick and choose the ingredients from the prior art to yield the claimed invention, with nothing more than the Examiner's personal opinion for rendering the

Appellants' claims as obvious. See In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988) ("cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.").

REJECTION OF CLAIM 10 UNDER 35 U.S.C. §103

Appellants further traverse rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Simon as applied to claims 15, 28-30 above, and further in view of Elias. Since claims 15 and 28 are believed to be patentable for the aforementioned reasons and Elias does not provide the deficiencies in Simon (providing no suggestion for the specific combination claimed), the Appellants submit that claim 10 is nonobvious in light of the prior art.

REJECTION OF CLAIMS 2, 3, 6-8, 16, 17, 20, 23, 26 & 33-36 UNDER 35 U.S.C. §103

Regarding the outstanding issue as to whether claims 2, 3, 6-8, 16, 17, 20, 23, 26 and 33-36 under 35 U.S.C. 103(a) are unpatentable over Simon as applied to claims 15, 28-30, 32 and in further view of Subbiah, the Appellants traverse the Examiner's rejection, because, as discussed above, Simon provides no teaching or suggestion for the combination disclosed in claims 15, 28-30 or 32. Subbiah does not supply the deficiencies in Simon, since Subbiah makes no reference to combining the specific ingredients in Applicants' claim 15. The mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680 (Fed. Cir. 1990).

Claims 4, 9, 11-13, 18, 19, 21, 22, 24, 25, and 32 were objected to but deemed allowable if rewritten in independent form. Since Appellants believe the independent claims from which these claims depend to be patentable, the Appellants have not amended such claims.

CONCLUSION

In light of the arguments presented above, the obviousness rejection of the independent claims 6, 10 and 15 and the corresponding dependent claims should be reversed. Specifically, the rejection of Claims 2, 4, 6-13, 15-26 and 28-36 should be reversed as they are unfounded and they are based on Examiner's personal opinion and on hindsight reconstruction. Accordingly, Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,



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APPENDIX: THE CLAIMS ON APPEAL

2. (Previously Presented) The composition of claim 6 in which the protease inhibitor is selected from the group consisting of triterpenoid-containing extracts, and active components thereof, phenolic-containing extracts and active components thereof, and protein-based extract and active components thereof.

4. (Previously Presented) The composition of claim 3 in which the protease inhibitor is selected from the group consisting of white birch extract, betulinol, betulinic acid, *Boswellia* extract, boswellic acid, and combinations thereof.

6. (Previously Presented) A composition for topical application to the skin comprising from 0.001 to 10% of at least one protease inhibitor selected from the group consisting of white birch extract, silver birch extract, *Boswellia* extract, bearberry extract, *Centella asiatica* extract, *Pygeum (Prunus) africanum* extract, betulinol, betulinic acid, boswellic acid, ursolic acid, olealonic acid, oleanol, asiaticoside, asiatic acid, madagassic acid, green tea extract, apple extracts, EGCG, ECG, catechins, phenylpropanoids, phloretin, soy protein, egg protease inhibitors, cholesterol sulfate, phytosterol sulfate, and combinations thereof, and from 0.001 to 10% of at least one cell differentiation enhancer in which the enhancer is sclareolide.

8. (Previously Presented) The composition of claim 6 comprising about 0.1 to about 1% of a protease inhibitor and about .05 to 1% cell differentiaion.

9. (Previously Presented) The composition of claim 8 in which the inhibitor is white birch extract, betulinol, or boswellic acid and the enhancer is sclareolide.

10. (Previously Presented) A composition for topical application to the skin comprising from 0.001 to 10% of at least one protease inhibitor in which the protease inhibitor is cholesterol sulfate and from 0.001 to 10% of at least one cell

differentiation enhancer selected from the group consisting of forskolin, sclareolide, 7-dehydrocholesterol, and Vitamin D3 analogs.

11. (Previously Presented) The composition of claim 10 which also contains at least one fatty acid, at least one ceramide, and at least one sterol.
12. (Previously Presented) The composition of claim 11 in which the fatty acid is a C12-C20 fatty acid.
13. (Previously Presented) The composition of claim 11 containing about 0.05 to 10% of each of cholesterol sulfate or phytoesterol sulfate, fatty acid, ceramidine, and sterol.
15. (Previously Presented) A composition for topical application to the skin comprising from 0.001 to 10% of at least one protease inhibitor selected from the group consisting of white birch extract, silver birch extract, *Boswellia* extract, bearberry extract, *Centella asiatica* extract, *Pygeum* (*Prunus*) *africanum* extract, betulinol, betulinic acid, boswellic acid, ursolic acid, olealonic acid, oleanol, asiaticoside, asiatic acid, madagassic acid, green tea extract, apple extracts, EGCG, ECG, catechins, phenylpropanoids, phloretin, soy protein, egg protease inhibitors, cholesterol sulfate, phytosterol sulfate, and combinations thereof and from 0.001 to 10% of at least one cell differentiation enhancer selected from the group consisting of forskolin, sclareolide, 7-dehydrocholesterol, and Vitamin D3 analogs, and a self tanning agent in which the self tanning agent is dihydroxyacetone.
16. (Previously Presented) The composition of claim 6 which further comprises at least one sunscreen.

17. (Previously Presented) A method for treatment or prevention of dry skin which comprises applying to the skin a composition according to claim 6.
18. (Previously Presented) A method for treatment or prevention of dry skin which comprises applying to the skin a composition according to claim 9.
19. (Previously Presented) A method for treatment or prevention of dry skin which comprises applying to the skin a composition according to claim 11.
20. (Previously Presented) A method for reducing or preventing skin's response to irritants or sensitizers comprising applying to the skin a composition of claim 6.
21. (Previously Presented) A method for reducing or preventing skin's response to irritants or sensitizers comprising applying to the skin a composition of claim 9.
22. (Previously Presented) A method for reducing or preventing skin's response to irritants or sensitizers comprising applying to the skin a composition of claim 11.
23. (Previously Presented) A method for protecting skin against effects of exposure to UV radiation comprising applying to the skin a composition of claim 6.
24. (Previously Presented) A method for protecting skin against effects of exposure to UV radiation comprising applying to the skin a composition of claim 9.
25. (Previously Presented) A method for protecting skin against effects of exposure to UV radiation comprising applying to the skin a composition of claim 11.
26. (Previously Presented) A method for protecting skin against effects of exposure to UV radiation comprising applying to the skin a composition of claim 16.

28. (Previously Presented) A method for tanning the skin without exposure to the sun comprising applying to the skin a composition according to claim 15.
29. (Previously Presented) The composition of claim 10 in which the protease inhibitor is selected from the group consisting of triterpenoid-containing extracts, and active components thereof, phenolic-containing extracts and active components thereof, and protein-based extract and active components thereof.
30. (Previously Presented) The composition of claim 10 in which the protease inhibitor is selected from the group consisting of white birch extract, silver birch extract, *Boswellia* extract, bearberry extract, *Centella asiatica* extract, *Pygeum* (*Prunus*) *africanum* extract, betulinol, betulinic acid, boswellic acid, ursolic acid, oleonic acid, oleanol, asiaticoside, asiatic acid, madagassic acid, green tea extract, apple extracts, EGCG, ECG, catechins, phenylpropanoids, phloretin, soy protein, egg protease inhibitors, cholesterol sulfate, phytosterol sulfate, and combinations thereof.
31. (Previously Presented) The composition of claim 30 in which the protease inhibitor is selected from the group consisting of white birch extract, betulinol, betulinic acid, boswellic acid, and combinations thereof.
32. (Previously Presented) The composition of claim 10 in which the cell differentiation enhancer is selected from the group consisting of forskolin, sclareolide, 7-dehydrocholesterol, and Vitamin D3 analogs.
33. (Previously Presented) The composition of claim 32 in which the enhancer is sclareolide.
35. (Previously Presented) The composition of claim 10 comprising about 0.1 to 1% of a protease inhibitor and about .05 to 1% cell differentiation enhancer.

36. (Previously Presented) The composition of claim 35 in which the inhibitor is white birch extract, betulinol, or boswellic acid and the enhancer is sclareolide.